

## **REMARKS**

### **Claim amendments**

The claims have been amended in response to the Examiner's objections for informalities and rejections under 35 USC § 112. New claims 16, 17, 18 and 19 have been added. Support for these claims may be found, e.g., in original claims 5, 6 and 11, respectively. No new matter has been introduced.

### **Claim objections**

1. The Examiner objected to claims 1-6 for informalities, as detailed in the Action. These claims have been amended to obviate the informalities.
2. The Examiner objected to claim 8 for informalities, as detailed in the Action. This claim has been amended to obviate the informalities.

### **Claim Rejections - 35 USC § 112**

- 3-4. The Examiner rejected claims 1-15 as being indefinite and failing to particularly point out and distinctly claim the subject matter of the invention. The objections in this respect are believed cured by the amendments.
5. The Examiner rejected claim 1 in that it is not clear whether the limitations after "characterized in that" are optional or required. Claim 1 has been amended to clearly define the limitations as required.
6. The Examiner rejected claims 5, 6 and 11 in view of the presence of "preferably". These claims have been amended. New claims 16-18 have been added, drawn to subject matter deleted from claims 5, 6 and 11.
7. The Examiner rejected claim 12 as being indefinite because the term "optionally" does

not further limit the claim. Claim 12 has been amended.

8. The Examiner rejected claims 14 and 15 for not setting forth any steps involved in the method/process. These claims have been amended.

**Claim Rejections - 35 USC § 101**

9-10. The Examiner rejected claims 14 and 15 for not being proper process claims. These claims have been amended.

**Claim Rejections - 35 USC § 102**

11-12. The Examiner rejected claims 1-6 and 14 under 35 USC 102(b) as being anticipated by nutraingredients-usa.com article (published July 2, 2003).

13. The Examiner cited as evidence "Enzymotec document" (downloaded from Enzymotec's website, pages 1-68).

14. The Examiner maintains that the nutraingredients-usa.com article teaches the enzymatically prepared fat base composition called InFat (page 1, paragraphs 1-3), which applicant discloses is the fat base composition claimed in claims 1-6 (specification, page 11, paragraph 5 and page 12, paragraph 3). The Examiner also refers to Enzymotec document (pages 5-7). With regard to claim 14, the Examiner maintained that the nutraingredients-usa.com article also teaches incorporation of InFat into infant formulas (article, page 1, paragraph 1 and 2), and also teaches that the new ingredient for infant formulas is said to be closer to the fat found in human milk, thus infant formula containing InFat would be deemed a substitute human milk fat composition.

Applicant respectfully traverses.

According to the cited nutraingredients-usa.com article:

"Nutritional oil company Enzymotec has launched a new ingredient for infant formulas said to be closer to the fat found in human milk.

InFat has a specific triglycerides' composition, with a high palmitic acid (carbohydrate chain) concentration, making it more nutritious for infants and also easier to blend with other oils.

"InFat is simply a better nutritional solution for babies. Incorporating it into infant formulas will increase baby's energy and calcium intake, one of the problems that infant formulas producers have to deal with," said Iris Bendek, the head of triglyceride research group at Enzymotec.

In vegetable oils, most of the palmitic acid is located at the alpha (sn-1,3) positions of the triglycerides. However, in human milk, most of the palmitic acid is in the beta (sn-2) position. InFat has been made with up to 90 percent of the total palmitic acid located at the beta (sn-2) position of the triglyceride, offering advantages for both nutrition and application, explained Bendek.

Vegetable oils cause the digested palmitic acid to form indigestible, insoluble soaps with calcium, resulting in significant calcium and energy loss for the infant, claims Bendek.

In the cited nutraingredients-usa.com article the triglyceride composition (InFat) is described as having up to 90% of total palmitic at sn-2. No specific sub-ranges are described. No values for palmitic acid at the sn-2 position are given.

The article does not describe a triglyceride composition with a total palmitic acid residues content of at most 38% of the total fatty acid residues and at least 60% of the fatty acid residues at the sn-2 position of the glycerol backbone are palmitic acid residues as claimed in claim 1.

Neither does the article describe a triglyceride composition in which at least 62% of the total palmitic acid residues are at the sn-2 position as in claim 2.

The article does not describe a triglyceride composition in which up to 70% of the total palmitic acid residues are at sn-2, as in claim 3.

The article does not describe a triglyceride composition in which at least 70% of the fatty acid residues at the sn-1 and sn-3 positions are oleic and other unsaturated fatty acid residues.

The article also does not describe triglyceride compositions in which at least 40-60% of the unsaturated fatty acid at positions sn-1 and sn-3 are oleic acid residues, as in claims 5 and 16.

The article also does not describe triglyceride compositions in which at least 6-17% of the unsaturated fatty acid at positions sn-1 and sn-3 are linoleic acid residues, as in claims 6 and 17.

Furthermore, the article does not mention that the fat bases are enzymatically prepared, as in present claims 1-6, 16 and 17.

It is to be noted that InFat is a trade mark used to mark many different fats. Attached is printed material showing diverse InFat products of the applicant (Annex A). The application at pages 11 and 12 refers to InFat as a general term, and not as a specific composition, with ranges of constituents as defined in claims 1-6, 16 and 17.

The Examiner's reference Enzymotec document at its web site is not clear. Applicants wishes to note that this site was built after the priority date of the present application.

For all and any of the said reasons, the nutraingredients-usa.com article does not anticipate the fat base composition of the present invention. It merely anticipates mentions InFat, a term used in the application for easy reference, and not to describe any specific product. The only product claimed is as defined in the claims.

#### **Claim Rejections - 35 USC § 103**

17. Joint inventors – The Examiner's comments regarding the requirements concerning jointy inventors is duly noted.

18. The Examiner rejected claims 7-10, 13 and 15 are as being unpatentable over the

nutraingredients-usa.com article in view of US Patent No. 4,876,107 (King et al.).

19. The Examiner relied on the article as detailed above in the rejection of claim 1.
20. The Examiner maintained that regarding claims 7-10, the article is taken as in connection with claims 1-6 above, and that it teaches that the fat base known as InFat can be incorporated into infant formulas and the specific composition of InFat makes it more nutritious to infants and also easier to blend with other oils (article, paragraphs 1 and 2). The Examiner states that the article does not specifically teach blending at least 25% of the fat base with up to 75% of at least one vegetable oil, wherein the blending oil is one of the claimed oils, and further does not specifically teach infant formula comprising at least one protein component.
21. The Examiner states that King teaches substitute milk fat composition for use in feeding young mammals and especially infants (Col. 1, lines 7-8), thus deemed a substitute human milk fat composition and an infant formula, wherein preferably the sn-2 position of the glycerol backbone consists substantially of palmitic acid, particularly 60-90% by weight of the total sn-2 fatty acids, and that 1,3-positions include unsaturated fatty acids, preferably largely consisting of oleic and linoleic acids (Col. 2' lines 30-33). King teaches that such an arrangement results from the rearrangement of vegetable fat via enzymes (Col. 3, lines 20-25). King further teaches that other fats may be included in the composition, including vegetable oils, for example sunflower oil and soy bean oil, having a high content of polyunsaturated fatty acids, to improve the dietary benefit of the compositions (Col. 2, lines 50-53). King further teaches that the substitute milk fat composition comprises 10-30% vegetable oil, which is below 75%, and the balance of the substitute milk fat composition would be the enzymatically rearranged vegetable fat composition (Col. 6, Claims 6 and 8). Therefore, the enzymatically rearranged vegetable fat composition would be present at at least 25% of the substitute milk fat composition. King further teaches that the resulting infant formula provides fat, protein and carbohydrate, wherein the fat normally found in such formulations is replaced by the enzymatically rearranged vegetable fat composition in accordance with the present invention (Col. 3, lines 30-35). With regard to claim 10, the Examiner states that since vitamins, minerals, nucleotides, amino acids and carbohydrates

are optional elements, King is deemed to meet the claimed limitations.

22. Therefore, the Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to blend at least 25% of the enzymatically prepared fat base composition with up to 75% of at least one vegetable oil including sunflower oil or soy oil, to provide an infant formula, as taught by King, because King teaches that the addition of vegetable oil to the substitute milk fat composition to prepare an infant formula provides high levels of polyunsaturated fatty acids, along with protein, and improves the dietary benefit of the composition, and further teaches that it is known to prepare infant formulas that comprise a substitute milk fat composition with the above claimed ratios of an enzymatically rearranged vegetable fat base composition and a vegetable oil. The Examiner concludes that one of ordinary skill in the art would have been motivated by King to add up to 75% vegetable oil to a substitute milk fat composition to improve the dietary benefits of the composition, thereby ensuring that infants being fed such infant formulas are receiving proper nutrition during feeding.

Applicant respectfully traverses.

As already explained above, the article [nutraingredients-usa.com](http://nutraingredients-usa.com) does not disclose the fat base composition of the invention, and its particularly advantageous fatty acid profile. Therefore, at the date of the application, the presently claimed fatty acid profile was not known. Therefore, it would not have been even theoretically possible for the man of skill in the art to combine the teachings of King with anything similar, let alone identical, with the fat composition of the invention, in order to prepare the blends of claims 7-10.

By way of explanation, it should be noted that three different compositions are concerned: (1) fat base, suitable for preparing fat blends that have a composition near that of human milk fat; (2) fat blends that are suitable for incorporation into infant formula, which blends comprise the fat base and, if necessary, blending oils; and (3) the final food product, e.g. infant formula, comprising the fat blend, and other ingredients.

Applicant wishes to draw attention to the fact that a main object of the invention is to provide cost-effective ingredients for preparing fat blends that can in turn be used as substitutes of human milk fat in infant foods, particularly formulas (e.g. [0034] and [0098]: "... the blends of InFat are also superior to the blends of Table 2 in terms of mimicking HMF as well as in the proportions of the concentrate needed to obtain each blend, keeping in mind that the concentrate, being a synthetic oil, is the major-cost component of the blend and hence should be kept to a minimum in order to achieve cost effectiveness of such a nutrition product."

As a result of the unique structure of the fat base of the invention, it can be used in relatively low amounts, to yield blends that are suitable as human milk fat substitutes. Thus, for example, the lowest amount of fat base (sample) used by King is 50% (Table 2, Blend 2). If comparing such blend with, for example, the blend using 30% fat base in the present application (see e.g., Example 2, InFat 1 and Table 1), applicant calculated that cost of production of a blend suitable as human milk fat substitute using 50% fat base, as in King, instead of only 30%, would be higher by more than 40%. Not only is the required amount of fat base lower, the actual saving when using the fat base of the invention is higher, in fact, because the fat base itself is cheaper to make. Other advantages of the fat base of the invention when used in blends are presented in Example 3 and Table 2, comparing to commercially available fat bases (Concentrates 1 and 2). The Examiner's attention is drawn to the fact that InFat is used in the application for various bases (concentrates), as well as blends (InFat1, InFat2, etc.,) which is commensurate with the explanation above that InFat is a range of products of Enzymotec, with characteristic features in common, but which may be with different specifications.

Although, as mentioned, the combination of the article and King would not yield blends known from King, and could not have been possible at all at the date of the application, some specific references to King are detailed as follows.

The blending oils are just standard vegetable oils that are used in order to achieve the full spectrum of fatty acids required for infant formulas. Since the cited article does not give any details of the fatty acid profile of the fat base, it is practically impossible to calculate what would

be the result of blending something with up to 90% palmitic acid residues at the sn-2 position with unknown quantities of vegetable oils. Furthermore, with a 90% level of palmitic acid residues at the sn-2 position, this fat base would not be cost effective.

With the above in mind, it should be noted that while the cited article mentions some advantages of "InFat" (in general, not any specific fat base) for infant formula, it does not mention blending at least 25% and less than 50% of the fat base with up to 75% other vegetable oils. To make blends, the fat base in King is used at higher relative amounts of at least 50%, whereas in the present application there are examples of 30%. Furthermore, the fat base in King (samples) are with >40% palmitic acid of total fatty acid while in the present application the upper limit is 38%.

The vegetable oils used in King (PK-Palm Kernel and SF-sunflower) are very low in palmitic and in palmitic at sn-2. Blending only 25% of their sample (fat base) with those vegetable oils will lead to blends with very low level of palmitic acid residues at sn-2. When using the blending oils King suggests (sunflower and palm kernel and soybean), necessarily higher amounts of fat base are required. With the fat base of the invention, other vegetable oils can be used for blending, which allows for the use of less fat base, and improved cost effectiveness.

Thus, any blends adapted from King would differ from blends of claims 7-10, in view of at least the differences between the present fat base (claim 1) and the fat bases of D4 ("samples" 1-4, Table 1) which are different from the fat base of the present invention, because, for example, the total palmitic acid content is more than 38%, as in the fat base of the present invention. Needless to say, any such blend would be more costly. Also the differences between the processes used for preparing the fat base, as detailed below with reference to the process claims, render the fat base of the present invention more cost-effective.

It is therefore respectfully submitted that the invention defined in claims 7-10 is unobvious from the nutraingredients-usa.com article in view of King.



23-24. With regard to claims 13 and 15, the above arguments apply with equal force.

25. The Examiner rejected claims 11 and 12 under USC 103(a) as being unpatentable over the nutraingredients-usa.com article in view of King and further in view of US Patent No. 5,371,253 (Cooper).

26. The Examiner applied the nutraingredients-usa.com article as above.

27. The Examiner stated that the article does not specifically teach the process for preparing the fat base composition as in claims 11 and 12.

28. The Examiner, as above, maintained that this document teaches a process of preparing an enzymatically rearranged fat composition comprising the steps of: (a) reacting an upper-melting fraction of palm oil, which is expected to be rich in palmitic acid, with oleic acid, in the presence of a lipase immobilized on Celite, which is deemed to be an insoluble catalyst. The Examiner notes that King also uses hexane in the process, but since claim 11 claims "comprising the steps of", this does not preclude the use of other elements also present in the process. King further teaches (b) removing the catalyst, and (c) distilling the free fatty acids. Since step (c) is optional, King is deemed to meet the claimed limitation. With regard to claim 12, the Examiner maintains that since the fractionation step is optional, King is deemed to meet the claim limitation.

29. The Examiner concludes that therefore it would have been obvious for the man of ordinary skill in the art at the time of the invention, for the process of preparing a fat base composition to have comprised the claimed steps, as taught by King, because King teaches that such steps result in an enzymatically rearranged substitute human milk fat composition wherein the sn-2 position consists substantially of palmitic acid residues and the sn-1 and sn-3 positions include unsaturated residues and further teaches that such a process is known and one of ordinary skill in the art would have expected a reasonable degree of success in using a known process of preparing an enzymatically rearranged substitute human milk fat composition for use in infant formula.

30. Regarding claim 11, the Examiner states that King does not specifically teach the step of (d) bleaching the oil after distilling.

31. The Examiner then states that Cooper teaches that processing steps such as bleaching filtration, deodorization and the like are techniques known in the art for refining natural vegetable or animal oils and fats and that products produced from fatty acids, such as palm oil and palm kernel oil, can be additionally purified or treated using such techniques.

32. The Examiner therefore concludes that it would have been obvious to the one of ordinary skill in the art at the time of the invention, for the process of preparing a fat base composition to have further comprised the step of bleaching, because Cooper teaches that bleaching is one of several techniques known in the art for refining natural vegetable or animal oils and teaches that such techniques can be used on products produced from palm oil or palm kernel oil. One of ordinary skill in the art would have been motivated by Cooper to use bleaching as a technique known in the art to refine oils and fats and would have expected a reasonable expectation of success in bleaching oil or fat in order to produce a more refined or treated final product.

Applicant respectfully traverses.

First, it should be noted that the cited article does not teach any process for preparing InFat. The article does not describe any process at all, and does not even mention or suggest that such process may be enzymatic. It may be noted that enzymatic process are not the only processes used for making rearranged oils and fats, for example, chemical processes are also abundantly applied. Furthermore, the article does not give any specifics of the product or its fatty acids profile. Therefore, as already argued above, the man of skill in the art could not have combined any documents when developing a process for preparing a fat base with the characteristics of claim 1, i.e. total palmitic acid residues content of at most 38% of the total fatty acid residues and at least 60% of the fatty acid residues at the sn-2 position of the glycerol backbone are palmitic acid residues as claimed in claim 1.

King neither teach nor suggests the preparation of a fat base having the characteristics of the fat base of claim 1.

Furthermore, the process of the present invention differs in that it does not involve the use of a solvent [cf. page 14 of the PCT publication, penultimate paragraph: "An important advantage of the process described herein is that it does not involve the use of solvents, which may leave potential toxic residues in the fat composition to be used in the preparation of infant formulas. Thus, the process of the invention yields a safer product." King uses solvent (hexane) in the fat base production while in the present application no solvent is used [cf. page 16 of the PCT publication, page 16, lines 19-20: "with no additional solvent".

In addition, in King, e.g. Example 2, the catalyst is pre-activated by the addition of water. This amount of water used probably causes a high hydrolysis. Example 2 of King describes a mixture of 100 grams upper melting fraction of palm oil with 200 grams of oleic acid. After the rearrangement 67% of free fatty acids FFA should have been obtained (200 of 300 grams), while in fact 80% were obtained, showing a high rate of hydrolysis. Further, King states that there are partial glycerides, meaning di- and mono-glycerides. The high amount of FFA and the presence of partial glycerides mean an ineffective and expensive process. For example, as described in Example 1 of the present application, the InFat fat base has more than 90% triglycerides while in King, as shown in Table 4, there are 18.7% of other glycerides (probably not triglycerides).

It is therefore respectfully submitted that the claimed process is inventive over the article, in view of King and further in view of Cooper.

Reconsideration and withdrawal of the rejections made in the Office Action is respectfully solicited and requested.

In light of the foregoing remarks, this application should be in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this

amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Further, it is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time, time sufficient, to effect a timely response, and shortages in this or other fees, be charged, or any overpayment in fees be credited, to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 7056-X08-022)

Respectfully submitted,

A handwritten signature in black ink that reads "Martin Fleit". The signature is written in a cursive, flowing style.

Martin Fleit, Reg. #16,900

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Attachment: ANNEX A